United States Court of Federal Claims

No. 15-200V
(Filed Under Seal: March 19, 2018)
Reissued: April 6, 2018[1]

MARIO CARUSO, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Vaccine Case; Motion for Review; Influenza Vaccine; *Althen*; Burden of Proof

OPINION

Ronald Craig Homer, Conway, Homer, P.C., Boston, MA, for petitioner.

Darryl R. Wishard, Vaccine/Torts Branch, Civil Division, United States Department of Justice, Washington, DC, for respondent.

SMITH, Senior Judge:

Petitioner, Mario Caruso, seeks review of a decision issued by Special Master Brian H. Corcoran denying his petition for vaccine injury compensation. Petitioner brought this action pursuant to the National Vaccine Injury Compensation Program, 42 U.S.C. §§ 300aa-10 et seq. (2012), alleging that petitioner developed acute disseminated encephalomyelitis ("ADEM") as a result of the trivalent influenza vaccine he received on October 16, 2012. The Special Master denied compensation, finding that petitioner had not met his burden of proof. *Caruso v. Sec'y of Health & Human Servs.*, 2017 WL 5381154 (Fed. Cl. Spec. Mstr. Oct. 18, 2017) (*Caruso*). Petitioner now moves for review of this decision. For the reasons that follow, the Court **DENIES** his motion.

[1] An unredacted version of this opinion was issued under seal on March 19, 2018. The parties were given an opportunity to propose redactions, but no such proposals were made.

I. BACKGROUND

A brief recitation of the facts provides necessary context.[2]

Mr. Caruso received the flu vaccine on October 16, 2012, when he was 64-years-old. Prior to receiving the vaccine, his medical history included prostate enlargement, hypolipoproteinemia,[3] varicose veins of the lower extremity with an ulcer, and sclerosis of the skin.[4] Subsequent to receiving the vaccine, Mr. Caruso's medical evidence did not indicate any immediate reaction to the vaccine for the 10 weeks following vaccination. On October 23, 2012, Mr. Caruso visited a physician at the Peachwood Medical Group ("PMG") to have his lipid levels checked, at which point he did not report any neurological issues or other symptoms.

At trial, Mr. Caruso's wife, Sylvia Caruso, testified that she noticed changes in Mr. Caruso's behavior around November 2012. Specifically, she stated that he struggled to move large items and began having difficulty with his vision during that period. She then testified that things progressively worsened and that petitioner started walking in an unstable way around the end of December 2012.

In late January of 2013, Mr. Caruso began seeking medical attention after he experienced a more acute incident, wherein he was shopping and his feet suddenly started to drag and he displayed an uneven gait like a "drunken sailor." On January 28, 2013, petitioner had an appointment with his nurse practitioner at PMG, at which he stated that he had been sporadically "walking funny," falling asleep in the evenings, and felt off balance, but denied paresthesia.[5] These medical records did not indicate that Mr. Caruso had been experiencing any symptoms prior to December 2012. Additionally, he denied experiencing blurred vision, double vision, photophobia,[6] headaches, and weakness. His exam results were deemed normal, but the nurse practitioner indicated that Mr. Caruso seemed "to slightly drag right tow [sic]. No specific abnormality but gait does not seem totally normal." Petitioner was diagnosed with dizziness and

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[2] As the basic facts here have not changed significantly, the Court's recitation of the background facts here draws from the Special Master's earlier opinion in *Caruso*.

[3] Hypolipoproteinemia is "the presence of abnormally low levels of lipoproteins in the serum, as in hypobetalipoproteinemia and Tangier disease." *Dorland's Illustrated Medical Dictionary* 903 (32nd ed. 2012) ("*Dorland's*").

[4] A varicose vein is "a dilated tortuous vein, usually in the subcutaneous tissues of the leg, often associated with incompetency of the venous valves." *Dorland's* at 2036. A varicose ulcer is "an ulcer on the leg due to varicose veins, such as a stasis ulcer." *Id.* at 1998. Sclerosis of the skin is "an induration or hardening, such as hardening of a part from inflammation, increased formation of connective tissue, or disease of the interstitial substance." *Id.* at 1680.

[5] Paresthesia is "an abnormal touch sensation, such as burning, prickling, or formication, often in the absence of an external stimulus." *Dorland's* at 1383.

[6] Photophobia is "abnormal visual intolerance of light." *Dorland's* at 1441.

a gait disorder, and diagnostic tests were ordered. A CT scan from February 1, 2013 found no significant abnormalities, and the results were deemed "unremarkable."

Mr. Caruso was again seen at PMG on February 8, 2013, complaining of dizziness, diplopia,[7] and gait difficulty. He was referred to a neurologist. On February 11, 2013, petitioner met with Dr. Loveneet Singh, at which point he complained of fatigue, vision changes, and gait problems. During the visit he displayed impaired coordination and diplopia, an inability to perform rapid alternating movements, a slow gait, and a need for support when walking. Dr. Singh opined that Mr. Caruso demonstrated evidence of upper motor neuron dysfunction, including cerebellar signs and gait ataxia.[8] Brain and cervical spine MRIs performed on March 2, 2013, showed multifocal signal abnormalities in the midbrain, brainstem, brachium pontis, cerebellum, and spinal cord. Some of the lesions enhanced,[9] and some cerebral volume loss was noted. The MRIs also showed both enhancing and non-enhancing signal abnormalities. There also appeared to be evidence of active inflammation on petitioner's spine, which suggested "active demyelinated plaques with breakdown of the blood brain barrier."

Mr. Caruso again met with Dr. Singh on March 11, 2013, at which point ADEM[10] and multiple sclerosis[11] ("MS") were included in his differential diagnosis. Dr. Singh ordered more testing, including lab work of petitioner's glucose and protein levels, a cell count, and an MS panel. The results of the testing were relatively normal, with no evidence of oligoclonal bands[12] and a negative MS panel.

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7 Diplopia is "the perception of two images of a single object . . . ." *Dorland's* at 525.

8 Ataxia is the "failure of muscular coordination; irregularity of muscular action." *Dorland's* at 170.

9 A lesion is "any pathological or traumatic discontinuity of tissue or loss of function of a part. *Dorland's* at 1025.

10 Acute disseminated encephalomyelitis ("ADEM") is "an acute or subacute encephalomyelitis or myelitis characterized by perivascular lymphocyte and mononuclear cell infiltration and demyelination; it occurs most often after an acute viral infection, especially measles, but may occur without a recognizable antecedent. It is believed to be a manifestation of an autoimmune attack on the myelin of the central nervous system. Symptoms include fever, headache, and vomiting; sometimes tremor, seizures, and paralysis; and lethargy progressing to coma that can be fatal. Many survivors have residual neurologic deficits." *Dorland's* at 613.

11 Multiple sclerosis is "a disease in which there are foci of demyelination throughout the white matter of the central nervous system, sometimes extending into the gray matter; symptoms usually include weakness, incoordination, paresthesias, speech disturbances, and visual complaints. The course of the disease is usually prolonged, so that the term multiple also refers to remissions and relapses that occur over a period of many years." *Dorland's* at 1680.

12 Oligoclonal means "pertaining to or derived from a few clones." *Dorland's* at 1317.

Additionally on March 11, 2013, petitioner visited Dr. Gary Walters, an ophthalmologist, at Eye Medical Center in Fresno, California. Dr. Walters noted in his records that petitioner's sudden onset of double vision and walking difficulties were reported to have begun two months prior, in January 2013. At this appointment, Mr. Caruso showed decreased vision (right eye 20/200; left eye 20/70), but those symptoms showed improvement throughout 2013.

Petitioner again visited Dr. Singh in July 2013, at which point the ADEM diagnosis was confirmed, but nothing in the medical records indicated that the flu vaccine played a part in its development. After a year of ongoing symptoms with no signs of progression in severity or evidence of additional developing lesions, Mr. Caruso sought a second neurological opinion. He saw Dr. Leslie Dorfman at the Stanford Hospital in Redwood City, California on June 23, 2014. Dr. Dorfman reviewed petitioner's MRIs and agreed that they were not indicative of MS. Dr. Dorfman also opined that ADEM was an "acceptable working diagnosis," but that he ultimately felt the true diagnosis for petitioner's symptoms remained unidentified.

Petitioner returned to Dr. Dorfman on July 25, 2014, at which point Dr. Dorfman noted that recent testing produced negative or normal results. Dr. Dorfman then opined that Mr. Caruso was likely suffering from an "atypical form" of ADEM, offering no signs as to its etiology, and he recommended that petitioner undergo steroid treatment, followed by IVIG[13] if the steroids proved ineffective. By August, petitioner reported improvement from the steroid treatment, and Dr. Dorfman proposed its continuation.

Additional medical records indicate that Mr. Caruso has continued to experience sequelae[14] from his 2012-13 symptoms. Some records suggest a relationship between the flu vaccine and petitioner's symptoms, but those records memorialize representations made by petitioner, rather than provide contemporaneous information provided to treaters when Mr. Caruso began seeking treatment in January 2013. MRIs from April 2015 confirm that no additional lesions have appeared since 2013, further corroborating the accuracy of the ADEM diagnosis.

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[13] Intravenous immunoglobulin ("IVIG") is a blood product used to treat patients with antibody deficiencies, including neurological disorders. Decision, at 6 (citing Clinical Uses of Intravenous Immunoglobulin, NCBI (2005), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1809480/ (last visited on Aug. 28, 2017)). It is commonly prescribed to treat diseases believed to be autoimmune in nature, increasing the effectiveness of an individual's immune response. *Id.*

[14] Sequelae are "any lesion[s] or affection[s] following or caused by an attack of disease." *Dorland's* at 1696.

On November 24, 2015, petitioner filed the expert report of Dr. Carlo Tornatore.[15] On June 16, 2016, respondent filed the expert report of Dr. Thomas Leist.[16] An entitlement hearing was held on April 21, 2017, and Special Master Corcoran denied petitioner's claim on October 18, 2017, finding that there was insufficient evidence to support an award of compensation. Decision of the Special Master (hereinafter "Dec.") at 22. Petitioner filed his Motion for Review (hereinafter "MFR") on November 17, 2017. Respondent filed its Response to petitioner's Motion for Review (hereinafter "Resp. to MFR") on December 18, 2017. Petitioner's Motion is fully briefed and ripe for review.

II. STANDARD OF REVIEW

Under the Vaccine Act, this Court may review a special master's decision upon the timely request of either party. *See* 42 U.S.C. § 300aa-12(e)(1)-(2). In that instance, the Court may: "(A) uphold the findings of fact and conclusions of law. . . , (B) set aside any findings of fact or conclusion of law. . . found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. . . , or, (C) remand the petition to the Special Master for further action in accordance with the court's direction." *Id*. at § 300aa-12(e)(2)(A)-(C). Findings of fact and discretionary rulings are reviewed under an "arbitrary and capricious" standard, while legal conclusions are reviewed *de novo*. *Munn v. Sec'y of Health & Human Servs.*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992).

This Court cannot "substitute its judgment for that of the special master merely because it might have reached a different conclusion." *Snyder ex rel. Snyder v. Sec'y of Dep't of Health &*

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[15] Dr. Tornatore is a board-certified neurologist. *See* Ex. 27, dated Nov. 24, 2015 ("Tornatore CV"). He graduated from Cornell University with a Bachelor of Arts in Neurobiology, and then attended Georgetown University Medical center where he received a Master of Science in Physiology. *See* Tornatore CV at 2; Tr. at 98. He subsequently graduated from medical school at Georgetown University School of Medicine, completed a residency in the Department of Neurology at Georgetown University Hospital, and completed a fellowship in molecular virology at the National Institutes of Health in Bethesda, Maryland. *See id.* Currently, he serves as Vice Chairman in the Department of Neurology at MedStar Georgetown University Hospital and as a Professor of Neurology at Georgetown University Medical Center. *See* Tornatore CV at 3; Tr. at 98-99.

[16] Dr. Leist attended the University of Zurich, where he obtained his Ph.D. in immunology and biochemistry as well as a post-doctorate degree in experimental pathologies. *See* Tr. at 188-89; *see also* Ex. B ("Leist CV"). He also completed a post-doctorate at the University of California, Los Angeles and attended medical school at the University of Miami. *See id.* He then completed a residency in neurology at Cornell University before becoming a fellow at the National Institutes of Health. *See* Tr. at 189. Dr. Leist is board certified in neurology and currently serves as a professor of neurology at Thomas Jefferson University in Philadelphia, Pennsylvania as well as directing the MS center and guiding the MS or the neuro-immunology fellowship program. *See id.*

Human Servs., 88 Fed. Cl. 706, 718 (2009). "Reversal is appropriate only when the special master's decision is arbitrary, capricious, an abuse of discretion, or not in accordance with the law." *Id.* Under this standard, a special master's decision "must articulate a rational connection between the facts found and the choice made." *Cucuras v. Sec'y of Dep't of Health & Human Servs.*, 26 Cl. Ct. 537, 541–42 (1992), *aff'd*, 993 F.2d 1525 (Fed. Cir. 1993) (citing *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962)). This standard is "highly deferential." *Hines v. Sec'y of Dep't of Health & Human Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991). "If the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate." *Id.*

III. DISCUSSION

Althen v. Secretary of Health & Human Services provides the evidentiary burden for petitioners attempting to succeed in a vaccine petition based on causation. *See generally Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274 (Fed. Cir. 2005). In order to prove causation-in-fact, a petitioner must

> show by preponderant evidence that the vaccination brought about [petitioner's] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Id. at 1278. In order to succeed, petitioners must provide a "reputable medical or scientific explanation" for their claim. *Id*.

Within this framework, petitioner makes two numbered objections to the October 18, 2017 decision. *See* MFR at 10, 26. First, petitioner asserts that the Special Master's decision to discount the fact testimony in its entirety was arbitrary, capricious, and an abuse of discretion. *Id.* at 10. Second, petitioner argues that the Special Master committed error in his *Althen* prong two analysis by failing to consider relevant evidence and requiring evidence that does not exist. *Id.* at 26.

A. Fact Testimony

In his Motion for Review, petitioner alleges that the Special Master's decision to discount the fact testimony in its entirety was arbitrary, capricious, and an abuse of discretion. MFR at 10. In making this argument, petitioner posits that the Special Master failed to address the *La Londe* factors. MFR at 16. Petitioner further argues that the Special Master "did not clearly explain his basis for affording no weight to [the] credible [fact witness] testimony." *Id*. at 18.

At the outset, the Special Master is not bound to follow the analytical framework articulated by this Court in *La Londe*. A decision of this Court only binds a special master in the

same case on remand. *Hanlon ex rel. Hanlon v. Sec'y of Dep't of Health & Human Servs.*, 40 Fed. Cl. 625, 630 (1998), *aff'd*, 191 F.3d 1344 (Fed.Cir.1999)); *Jones v. Sec'y of Dep't of Health & Human Servs.*, 78 Fed. Cl. 403 (2007); *Snyder ex rel. Snyder*, 88 Fed. Cl. at 719, n.23.

Further, petitioner is incorrect in asserting that Special Master Corcoran failed to discuss the *La Londe* factors. The Special Master specifically cited to *La Londe*, stating the following:

> In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist.

Dec. at 15; *La Londe v. Sec'y of Health & Human Servs*., 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). The Special Master then goes on to state that "[i]n making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination." Dec. at 15 (citing *Burns v. Sec'y of Health & Human Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993)).

Special Master Corcoran ultimately determined that, while the fact witnesses were credible individuals, "the instances they described are too anecdotal and inconclusive to deem significant (especially without any additional corroborative proof)," particularly where "their oral recollections are compared with Petitioner's more precisely-documented, medically-tested symptoms referenced in the January and February 2013 medical records." Dec. at 18. The Special Master expanded on this by stating that the fact witness testimony "was not sufficiently corroborated by other circumstantial evidence to elevate it over contemporaneous record proof that clearly establishes a later onset date." *Id.* However, he did determine that there exists an overlap between the contentions of the fact witnesses and the information in the medial records in December 2012, thereby determining that the "ADEM-related symptoms began no earlier than late December 2012. . . , as confirmed by witness testimony and corroborated by medical records from around the time Petitioner first sought treatment for his gait problems in January 2013." *Id.*

Petitioner specifically points to a journal entry dated March 9, 2013, in which petitioner's wife states that Mr. Caruso began having neurological symptoms in November 2012. MFR at 21-22. Petitioner takes issue with the fact that the Special Master did not afford this journal entry more weight than he afforded to the contemporaneous medical records, which support a late-December or early-January onset. MFR at 22; Dec. at 18, n.18. While petitioner might prefer more weight be afforded to Mrs. Caruso's March 9, 2013 journal entry, the Special Master clearly evaluated its relevance in establishing an onset period.

Determining what weight should be afforded to the testimony of a fact witness, expert witness, or medical records is a finding well within the discretion of the Special Master, and this Court will not endeavor to infringe upon that well-established discretion.

B. *Althen* Prong Two

In addition to arguing that the Special Master's treatment of the fact testimony was arbitrary, capricious, and an abuse of discretion, petitioner also asserts that the Special Master erred as a matter of law by failing to consider relevant evidence and requiring evidence that does not exist in his analysis of *Althen* prong two. Specifically, petitioner alleges that the Special Master "failed to consider relevant evidence in determining whether the petitioner met his burden of establishing a logical sequence of cause and effect between the vaccination and the injury," and that "in doing so the Special Master's conclusion amounted to his own speculation and, thus, was arbitrary, capricious, and an abuse of discretion." MFR at 26-27. Petitioner also asserts that, contrary to law, the Special Master "elevated petitioner's burden of proof by requiring medical literature specifically describing [Mr. Caruso's] clinical picture—and not ADEM generally—occurring as a result of vaccination." *Id*. at 27.

As an initial matter, *Althen* prong two requires "a logical sequence of cause and effect showing that the vaccination was the reason for the injury." *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1324 (Fed. Cir. 2006) (quoting *Althen*, 418 F.3d at 1278). "'A logical sequence of cause and effect' means what it sounds like—the claimant's theory of cause and effect must be logical." *Id*. at 1326. While a finding of causation "must be supported by a sound and reliable medical or scientific explanation," causation "can be found in vaccine cases. . .without detailed medical and scientific exposition on the biological mechanisms." *Knudsen v. Sec'y of the Dep't of Health & Human Servs*., 35 F.3d 543, 548-49 (Fed. Cir. 1994). However, petitioners must still provide a "reputable medical or scientific explanation" for their claim. *Althen*, 418 F.3d. at 1278.

The Special Master acknowledged that "preponderant evidence better supports the ADEM diagnosis," and that "there is ample record evidence supporting the diagnosis of ADEM over other central nervous system demyelinating diseases like MS (*i.e.* nature of lesions, lack of oligoclonal bands), and the lack of recurrent or new lesions later further supports ADEM." Dec. at 19. However, the Special Master also found that "the most reliable evidence concerning Petitioner's diagnosis is *not* supportive of the causation theory he has (successfully) presented." *Id.* at 20 (emphasis in original). The Special Master expanded on this in the following way:

> Mr. Caruso's combination of symptoms, imaging evidence, and other test results led skilled treaters to adopt ADEM as the proper diagnosis, and I find sufficient preponderant evidence supports that conclusion (especially in light of Dr. Dorfman's views expressed in the summer of 2014, which had the benefit of a more expansive record to review than what had been available to initial treaters). But because Petitioner's symptoms were inconsistent with ADEM as it is most commonly understood, it becomes more difficult to simply assume that the same

> vaccine association applicable to "normal" cases of the disease applies here. Indeed, the literature offered to explain a vaccine's role in causing ADEM largely if not exclusively discusses the acute form of the disease, beginning within a month of infection or vaccination – *not* what the facts show Mr. Caruso experienced.

Id.; S. Tenembaum, et al., *Acute Disseminated Encephalomyelitis: A Long Term Follow-Up Study of 84 Pediatric Patients*, 59 Neurology 8: 1224-31, at 1224 (2002), filed as Ex. 26C (ECF No. 25-1); F. Noorbakhsh, et al., *Acute Disseminated Encephalomyelitis: Clinical and Pathogenesis Features*, 29 Neurologic Clinics 759-780, at 761 (2008), filed as Ex. 26B (ECF No. 25-1).

As the Special Master noted, "the symptoms of ADEM appear abruptly—that is, between one and two week[s] after the triggering event—in the overwhelming majority of cases." Dec. at 20 (citing *Stillwell v. Sec'y of Health & Human Servs.,* No. 11-77V, 2013 WL 4540013, at *16 (Fed. Cl. Spec. Mstr. June 17, 2013), *mot. for review den'd,* 118 Fed. Cl. 47 (2014)). The Special Master also noted that "[n]ot only was Petitioner outside the usual demographic group experiencing the disease (the very young), but his symptoms did not manifest acutely or suddenly, but instead unfolded more slowly and haltingly." *Id*. Then, the Special Master pointed out that even "had I accepted Petitioner's allegation that onset of ADEM occurred in November (and thus closer in time to vaccination), the progression of his symptoms would appear even *less* like classic ADEM, since his medical history would then constitute a series of somewhat mild neurologic symptoms (some weakness, vision difficulty), later leading to more concerning gait dysfunction that slightly improved before progressively worsening a month later." Finally, the Special Master concluded that "[p]etitioner has not demonstrated that reliable science linking vaccines like the flu vaccine to ADEM applies to his own circumstances, which present a more halting form of the condition." *Id*. at 21.

Traditionally, "Special Masters have broad authority in building a record for decision in vaccine cases and enjoy 'flexible and informal standards of admissibility of evidence.'" *Hunt v. Sec'y of Health & Human Servs.*, 123 Fed. Cl. 509, 519 (2015) (citing *Davis v. Sec'y of Health & Human Servs.*, 94 Fed. Cl. 53, 65 (2010), *aff'd in part, rev'd on other grounds*, 420 F. App'x. 973 (Fed. Cir. 2011) (quoting 42 U.S.C. § 300aa–12(d)(2)(B))). Special Masters need not discuss every scintilla of evidence when issuing a decision. As such, "[t]his Court will not substitute its judgment for that of the Special Master when the Special Master considered all of the pertinent evidence, including many of the particulars cited by Petitioner." *Vaughan on Behalf of A.H. v. United States*, 107 Fed. Cl. 212, 220 (2012). While it is clear that petitioner takes issue with the way that the Special Master *weighed* the evidence presented to him, Special Master Corcoran clearly *considered* all of the pertinent evidence provided. This Court cannot reweigh the evidence at hand to arrive at a new conclusion without infringing upon the great deference afforded special masters in making compensation decisions.

IV. CONCLUSION

This Court finds that petitioner has not met his burden of proof in alleging that his October 16, 2012 influenza vaccine resulted in his acute disseminated encephalomyelitis. For the foregoing reasons, the Court **DENIES** petitioner's Motion for Review.[17]

IT IS SO ORDERED.

s/ *Loren A. Smith*
Loren A. Smith,
Senior Judge

[17] This opinion shall be unsealed, as issued, after April 2, 2018 unless the parties, pursuant to Vaccine Rule 18(b), identify protected and/or privileged materials subject to redaction prior to that date. Said materials shall be identified with specificity, both in terms of the language to be redacted and the reasons therefor.